UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,964	07/08/2004	Keizo Sugasawa	07385.0030	3433

22852 7590 08/28/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,964	SUGASAWA ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 10-13 and 5-7, 14-17 reading on the elected compounds in the reply filed on Jun 11, 2007 is acknowledged. The traversal is on the ground that the subject matter wherein Ar^2 is pyridyl in claim 13 is not included in the grouping. The inadvertent omission of the pyridyl compounds of claim 13 is hereby corrected. The scope of group I would be Ar^2 as delineated in claim 6, i.e. phenyl or moncyclic aromatic heterocycles.

Claims 10-13 and claims 5-9, 14-17 reading on R4 is formula II X is $C(R^{27})R^{28}$ or NR^{26}, m=n=2, Ar^2 is phenyl or moncyclic aromatic heterocycles are prosecuted. Claims 1-4, and the remaining subject matter of claims 5-9, 14-17 are withdrawn from consideration per 37 CFR 1.142(b).

2. A claim to the priority benefit of the foreign priority JP 02-10413 and JP 02-10447 is denied because no certified translation of the priority documents were submitted.

3. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what do the terms such as "as an active ingredient", "used as an agent" "used as a therapeutic agent" or "a c-Mpl ligand" are referring to. Please note that if claims 14-17 are drawn to pharmaceutical composition, then, the dosage of the active ingredient and carrier was not clearly incorporated. Are the terms above referring to "therapeutically effective amount" "platelet number increasing effective amount" "an effective amount for treating thrombo-cyctopenia" or "a c-Mpl Ba-F3 cell proliferative effective amount"? Clarification is requested. It is recommended that proper dosage be incorporated in the claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5-11, 14-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Muto et al. CA 137:63257.

See RN 439146-08-4 and RN 439146-12-0 as pharmaceutical products.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0077697.

Please note that US 2004/0077797 have a different inventive entity, thus would constitute a 102(e) reference. Please not the piperidin/piperazinyl species of the whole reference anticipated the instant claims.

Claims 5-17 are directed to the same invention as that disclosed in commonly assigned US 2004/0077697. The issue of priority under 35 U.S.C. 102(f) or (g) of this identical invention (anticipatory compounds) must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. Whether the claims of the pregrant application is still pending has no effect in this situation since the pregrant publication served as evidence showing the "another" was in possession and reduced to practice at the time the instant invention was made thus, under 35 U.S.C. 102(f) or (g) and not an extension of monopoly. Whether any continuation was filed and the scope of the claims must also be submitted.

Failure to comply with this requirement will result in a holding of abandonment of this application.

3. Claims 5-12, 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of non-enablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

The invention is drawn to enormously structural diverse compounds of formula V for the utility of increasing platelet or treating thrombocytopenia.

The state of the art and predictability

Making and using compounds in physiological manipulation of pathology/disorder is highly unpredictable. Biological systems such as receptor bindings are very rigid which requires very specific size, configuration and electrical charge. It is very much like a lock and key situation, the key being the claimed compounds.

It is documented in the prior art that when Ar2 is indoly, the compounds have CCK antagonistic activity (US 5,380,736). It is also documented that when the X is O in formula II, or the X is NR26 and R26 is phenyl, the compounds have effectiveness against epilepsy or allergy (see CA 140:42203, CA 140:42216). It is also documented that when R3 is furanyl, Ar2 is pyridyl, the compound has A2A receptor antagonistic activity (see CA 143:133362, please note compounds anticipates the claims) or such compounds have efficacy in treating sleep disorder (CA 146:229330). The CA abstracts although are published after the filing of the instant

application, but are "evidence" showing the diverse and unpredictable nature of compounds with a thiazolyl core.

Therefore, per ponderous of documents evidenced that the structure of compounds embraced by the instant claims having enormous diversified biological activity and no commonality can be drawn without support with factual evidence using testing data.

The amount of guidance and working examples

In the specification on page 34, limited compounds have been tested for c-Mpl BaF3 proliferation activity. The tested compounds are limited to those encompassed in claim 13. In view of the extremely diverse and unpredictable nature of the structure and utility relationship evidence in the prior art, such limited exemplification failed to provide sufficient support for the broad scope as claimed. Note that In re Fischer 166 USPQ 18 or Ex parte Dash 27 USPQ2d 1481 indicated that the more unpredictable the field of activity, more enablement by way of specific examples is necessary in order to establish enablement for broad scope. Furthermore, the Takayama et al. (CA 142:240425) evidenced that the X is O compounds was in Takayama's possession while applicants showed no compounds of such scope, therefore, applicants have not demonstrated that applicants are in possession of the broad generic scope with sufficient assurance in providing adequate representative examples with myriad of structure encompassed by the broad claims.

The specification failed to provide those having ordinary skill in the art reasonable assurance as by adequate representative examples that myriad of compounds falling within the generic scope of the claims will have identical activity as those of claim 13.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 22, 2007

Celia Chang
Primary Examiner
Art Unit 1625